

REMARKS / ARGUMENTS

1. Claims Currently Pending

Claims 1-12 are pending.

2. 35 USC 112, first paragraph, failure to comply with written description requirement

Claims 1-12 as amended stand rejected under 35 USC 112, first paragraph, for failure to comply with the written description requirement. The action states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The action does not, however, specify what subject matter is being claimed which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. For this reason applicant cannot respond to this basis for rejection. Clarification is requested. In the absence of such clarification the rejection must be regarded as being without basis.

It is respectfully asserted that the more limited scope of the currently amended claims does not lack antecedent basis in the application. The amendments made in claims, which diminish their scope, are supported by specific, antecedent basis in the specification such as preferred embodiment or subgeneric description. Applicants, in making the amendments have not engaged in unsupported mixing and matching.

As explained in the previous response, in claim 1, as now amended, the definitions of X, U, V and W have been reduced in scope. Basis for so amending the definitions of these groups can be found on page 19 of the specification, under point (iii), where it is said, "...while in all the embodiments mentioned above those compounds wherein (iii) A denotes an oxygen atom, X denotes an oxygen atom, an imino or methylene group, U denotes a trifluoromethyl or pentafluoroethyl group, V denotes an amino or hydroxy group and W denotes a hydrogen, chlorine or bromine atom or a trifluoromethyl group, are of most particularly outstanding importance." Thus, the amendments do have antecedent basis in the specification. The

specification does contain a preferred subgeneric description which provides antecedent basis for the amendments.

Dependent claims 2-8 and 10-12 are similarly restricted in scope, as they incorporate by reference the definitions of X, U, V and W found in claim 1.

3. Lack of Enablement Basis for Rejection (“hydrates”)

The rejection of claims 1-11 under 35 USC 112, first paragraph, for lacking enabling support for hydrates is rendered moot by the elimination of the phrase “or hydrate” from claim 1. Applicant respectfully maintains that, in view of the teachings of Applicants' specification and of the general knowledge in the art at the time the invention was made, those skilled in the art would know, in general, how to make and use water-containing crystalline forms of the claimed compounds (hydrates) without undue burden. The elimination of the phrase “or hydrate” from claim 1 should be understood as a mere acknowledgement that applicant is not claiming any specific water-containing polymorph (hydrate) of any specific compound of formula I. In making this amendment it is not the intention of the applicant to remove hydrates from the generic scope of the claims. It is respectfully asserted that claims 1-11 as amended literally read on compounds of formula I in all their possible physical forms, including crystalline forms that include water in the crystal lattice (hydrates).

4. Lack of Antecedent Basis for “reducing the frequency of headache”

Claims 11 and 12 also stand rejected under 35 USC 112, first paragraph, “for lacking antecedent basis of the claimed term ‘treating or reducing the frequency of headache, migraine headache or cluster headache’”.

It is not understood how such basis for rejection can be applied to claim 11, as the phrase “treating or reducing the frequency of headache, migraine headache or cluster headache” does not appear in claim 11.

It is believed that the rejection of claim 12 is rendered moot by the amendments made in claim 12, as the claim no longer contains the phrase “treating or reducing the frequency of headache, migraine headache or cluster headache” .

5. Lack of Antecedent Basis for “host having an increased risk”

It is believed that the rejection of claim 12 is rendered moot by the amendments made in claim 12, as the claim no longer contains the phrase “host having an increased risk of suffering from a headache, migraine headache or cluster headache. Claim 12 as amended reads on a “method for treating headache, migraine headache or cluster headache” without specifying the nature of the host being treated.

6. Rejections Under 35 USC 103

The rejections under 35 USC 103 have been maintained only because the amendments made in claims 1-10 are asserted to introduce new matter and because it is asserted these amendments must be reversed, restoring the claims to their former state. The claims have not been amended so as to restore them to their former state because it is not agreed that the amendments have introduced new matter. As noted above, in numbered point 2, the outstanding action does not explain with sufficient specificity what amendments have introduced new matter, and why such matter is believed to be new. The burden is on the Office to justify the new matter rejection. In the absence of such justification it must be assumed that the rejection is without basis and that the claims can remain as presently amended. It is respectfully asserted that unless and until the new matter rejection is shown have adequate basis, so that the claims must be restored to their former state, the amendments made in the claims will avoid the basis for rejection under 103.

7. Obviousness-type Double Patenting

The rejections for obviousness-type double patenting have been maintained only because the amendments made in claims 1-10 are asserted to introduce new matter and because it is asserted these amendments must be reversed, restoring the claims to their former state. Once again, the claims have not been amended so as to restore them to their former state because it is not agreed that the amendments have introduced new matter. As noted above, in numbered

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point 2, the outstanding action does not explain with sufficient specificity what amendments have introduced new matter, and why such matter is believed to be new. The burden is on the Office to justify the new matter rejection. In the absence of such justification it must be assumed that the new matter rejection is without basis and that the claims can remain as presently amended. It is respectfully asserted that unless and until the new matter rejection is shown have adequate basis, so that the claims must be restored to their former state, the amendments made in the claims will avoid obviousness-type double patenting.

Respectfully submitted,

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